IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Toshiro OMORI et al.** Group Art Unit: **1655**

Application Number: **10/511,725** Examiner: **Amy Lynn Clark**

Filed: **October 19, 2004** Confirmation Number: **2520**

For: **COMPOSITION OBTAINED FROM BARLEY SHOCHU STILLAGE AND HAVING ACTIVITY OF INHIBITING ONSET OF ALCOHOLOC HEPATOPATHY AND ACTIVITY OF HEALING IT AS WELL AS EXCELLENT PALATABILITY, AND PROCESS FOR PRODUCING THE SAME**

Attorney Docket Number: **042872**
Customer Number: **38834**

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Toshiro OMORI, currently residing at 704-4 Oaza Kuzuhara Usa-shi Oita, Japan, declare as follows:

On March, 1985 I graduated from Kyushu University Agricultural Department, faculty of Agricultural Chemistry;

On April 1985 I joined the Sanwa Shurui Co., Ltd.;

From April 1989 to December 1989 I was a Trainee at National Tax Administration Agency's brewing laboratory;

On March 1995 I received a Ph.D. degree in Agriculture from Kyushu University,

From October 1996 to April 1998 I was a visiting Fellow at University of California Davis;

On April 1998 I was the General Manager of Laboratory Department at Sanwa Shurui Co., Ltd.;

On April 1999 I was the Deputy General Director of Laboratory at Sanwa Shurui Co., Ltd.;

On January 2001 I was CEO of Barley Fermentation Technologies, Inc.;

October 2003 I was Director of Laboratory at Sanwa Shurui Co., Ltd.;

In 1995 I received the Brewing Society of Japan's "Technology Award";

I am familiar with the prosecution of the present U.S. Patent Application;

I have reviewed and am familiar with Japanese Published Unexamined Application 2000-342247 to Omori et al (hereinafter "Omori '247"). I am the first named inventor of Omori '247; and

The following experimentation was conducted under my supervision and control by Kei HAYASHI at the Sanwa Shurui Co., Ltd. Brewing Research Laboratory;

Kei HAYASHI, is employed at the Sanwa Shurui Co., Ltd., Brewing Research Laboratory, is an inventor of the present application, and is familiar with the prosecution of the present U.S. Patent Application and with Japanese Published Unexamined Application 2000-342247 to Omori et al (hereinafter "Omori '247").

The following experimentation was conducted to show the ingredient composition of compositions obtained by the process of the present application and the ingredient compositions obtained by the process indicated in the Omori '247 reference.

Noted below is the experimental result comparing the ingredient composition of an unadsorbed fraction comprising a bypassed solution showing an unadsorptive property obtained by performing an adsorption separation process by passing the barley shochu stillage, as is, through a column filled with an aromatic synthetic adsorbent, indicated in Example 1 (Composition A) and an unadsorbed fraction comprising a bypassed solution showing an

unadsorptive property obtained by performing an adsorption separation process by passing the barley shochu stillage, as is, through a column filled with a methacryl synthetic adsorbent indicated in Example 2 (Composition B) representative of the present application, and an unadsorbed fraction comprising a bypassed solution showing an unadsorptive property, obtained by performing an adsorption separation process by passing the barley shochu stillage, after condensed to 1/3, through a column filled with an aromatic synthetic adsorbent indicated in Example 1 (Composition C) of the Omori '247 reference.

No. 1 Method of Preparation

Pursuant to the indication in the specification of the present application, barley shochu stillage indicated below was prepared.

1. Manufacturing of Starting Ingredient (barley shochu stillage)

As a raw material of barley, barley (70% polished) was used.

(1) Manufacturing of Koji

Barley koji was manufactured by causing barley to absorb 40% by weight of water, steaming for 40 minutes, then cooling to 40 °C, inoculating with 1 kg of seed malt (white-koji mold) per ton of barley, and maintaining at 38 °C, RH 95% for 24 hours, and at 32 °C, RH 92% for 20 hours.

(2) Manufacturing of Steamed Barley

The steamed barley was manufactured by causing barley to absorb 40% by weight of water, steaming for 40 minutes, then cooling to 40 °C.

(3) Manufacturing of Barley Shochu and Barley Shochu Stillage

In the first stage of preparation, 3.6 kL of water and 1kg (wet weight) of cultured strain of shochu yeast was added to the barley koji (3 ton of barley) manufactured by the method noted above to obtain a primary mash. The primary mash was then subjected to 5 days of fermentation (first step of fermentation). Next, in the second stage of preparation, 11.4 kL of water and steamed barley (7 ton in barley) manufactured by the method noted above were added to the above mentioned primary mash, which had finished the first step of fermentation, and then subjected to 11 days of fermentation (second step of fermentation). The fermentation for both first stage and second stage were conducted at the temperature of 25 °C. The secondary mash obtained after the second step of fermentation was subjected to single distillation, and 10 kiloliters of barley shochu and 15 kiloliters of barley shochu stillage were obtained. The barley shochu stillage obtained was used in the experiment below.

2. Method of Preparation of Composition A

An unadsorbed fraction comprising a bypassed solution showing an unadsorptive property obtained by performing an adsorption separation process by passing the barley shochu stillage, as is, through a column filled with AMBERLITE XAD-16 (an aromatic synthetic adsorbent) (The same method as Example 1 of the present application).

For the purpose of use the experiment below, the above mentioned liquid fraction obtained from barley shochu stillage was divided into an adsorbed fraction to AMBERLITE XAD-16 and unadsorbed fraction to AMBERLITE XAD-16, according to the following method.

The barley shochu stillage was centrifuged under conditions of 8,000 rpm and 10 minutes to form a liquid fraction of the barley shochu stillage, and 25 L of the liquid fraction

and 10 L of deionized water were passed in this order through a column (resin volume 10 L) filled with an aromatic synthetic adsorbent AMBERLITE XAD-16 manufactured by Rohm and Haas (formerly Organo), to obtain an eluate comprising an unadsorbed fraction showing an unadsorbability to the synthetic adsorbent of the column. The resulting unadsorbed fraction was freeze-dried to obtain a freeze-dried powder (Composition A).

3. Method of Preparation of Composition B

An unadsorbed fraction comprising a bypassed solution showing an unadsorptive property obtained by performing an adsorption separation process by passing the barley shochu stillage, as is, through a column filled with AMBERLITE XAD-7 (a methacryl synthetic adsorbent) (The same method as Example 2 of the present application).

For the purpose of use in the experiment below, the above mentioned liquid fraction obtained from barley shochu stillage was divided into an adsorbed fraction to AMBERLITE XAD-7 and unadsorbed fraction to AMBERLITE XAD-7, according to the following method.

The barley shochu stillage was centrifuged under conditions of 8,000 rpm and 10 minutes to form a liquid fraction of the barley shochu stillage, and 25 L of the liquid fraction and 10 L of deionized water were passed in this order through a column (resin volume 10 L) filled with a methacrylic synthetic adsorbent AMBERLITE XAD-7 manufactured by Rohm and Haas (formerly Organo), to obtain an eluate comprising an unadsorbed fraction showing an unadsorbability to the synthetic adsorbent of the column. The unadsorbed fraction was freeze-dried to obtain a freeze-dried powder (Composition B).

4. Method of Preparation of Composition C

An unadsorbed fraction comprising a bypassed solution showing an unadsorptive property, obtained by performing an adsorption separation process by passing the barley shochu stillage, after condensed to 1/3, through a column filled with SEPABEADS SP850 (an aromatic synthetic adsorbent).

For the purpose of use in the experiment below, the above mentioned liquid fraction obtained from barley shochu stillage was divided into an adsorbed fraction to SEPABEADS SP850 and unadsorbed fraction to SEPABEADS SP850, according to the following method.

The barley shochu stillage was centrifuged under conditions of 8,000 rpm and 10 minutes to form a liquid fraction of the barley shochu stillage, and 25 L of the liquid fraction and 10 L of deionized water were passed in this order through a column (resin volume 10 L) filled with an aromatic synthetic adsorbent SEPABEADS SP850 manufactured by Mitsubishi Chemical Corp., to obtain an eluate comprising an unadsorbed fraction showing an unadsorbability to the synthetic adsorbent of the column. The resulting unadsorbed fraction was freeze-dried to obtain a freeze-dried powder (Composition C).

No. 2 Analysis of Ingredient Composition of Composition A through C

The ingredient composition of the above mentioned Composition A [an unadsorbed fraction comprising a bypassed solution showing an unadsorptive property obtained by performing an adsorption separation process by passing the barley shochu stillage, as is, through a column filled with AMBERLITE XAD-16 (an aromatic synthetic adsorbent)], Composition B [An unadsorbed fraction comprising a bypassed solution showing an unadsorptive property obtained by performing an adsorption separation process by passing the

barley shochu stillage, as is, through a column filled with AMBERLITE XAD-7 (a methacryl synthetic adsorbent)], and Composition C [An unadsorbed fraction comprising a bypassed solution showing an unadsorptive property, obtained by performing an adsorption separation process by passing the barley shochu stillage, after condensed to 1/3, through a column filled with SEPABEADS SP850 (an aromatic synthetic adsorbent)], were analyzed pursuant to the indication in the present application (analysis of analytical material). A composition of amino acids, a composition of free amino acids, a composition of free saccharides, a composition of polysaccharides and a composition of organic acids constituting peptides were measured for each composition.

The composition of amino acids constituting the peptides was measured with an amino acid automatic analyzer (AMINO ACID ANALYZER L-8500A manufactured by Hitachi Ltd.) after acid decomposition using hydrochloric acid, the composition of free amino acids with the amino acid automatic analyzer, the composition of free saccharides by HPLC, the composition of polysaccharides by HPLC through hydrolysis with hydrochloric acid, and the composition of organic acids by HPLC.

The results of analyzing of each of the above mentioned ingredient composition (based on dry weight) of Compositions A through C are indicated in Tables 1 through 3.

No. 3 The Results of Analyzing Ingredient Composition of Compositions A through C

The results of analyzing ingredient composition of Composition A are shown in the attached Table 1.

The results of analyzing ingredient composition of Composition B are shown in the attached Table 2.

The results of analyzing ingredient composition of Composition C are shown in the attached Table 3.

No. 4 Conclusion

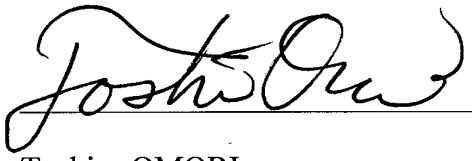
As shown in Tables 1 through 3, there is no overlap in ranges obtained by taking three measurements of each ingredient of an unadsorbed fraction comprising a bypassed solution showing an unadsorptive property, obtained by performing an adsorption separation process by passing the barley shochu stillage, after condensed to 1/3, through a column filled with SEPABEADS SP850 (an aromatic synthetic adsorbent) (Composition C), and three measurements of each ingredient of an unadsorbed fraction comprising a bypassed solution showing an unadsorptive property obtained by performing an adsorption separation process by passing the barley shochu stillage, as is, through a column filled with AMBERLITE XAD-16 (an aromatic synthetic adsorbent) (Composition A) and an unadsorbed fraction comprising a bypassed solution showing an unadsorptive property obtained by performing an adsorption separation process by passing the barley shochu stillage, as is, through a column filled with AMBERLITE XAD-7 (a methacryl synthetic adsorbent)] (Composition B). From this, it is evident that the compositions obtained by the method indicated in the present application differ from the composition obtained by the method indicated in Omori '247, not only in its method of preparation but also in its ingredient composition.

Further, as evident from the result shown in Table 3, regarding Composition 3's organic acids, it has been confirmed that the values are outside of the scope of the ingredient composition of compositions which relate to the present invention as claimed in the present application and as indicated in Table 7 and Table 8 of the present application.

From the above, it has been confirmed that the composition obtained by the method indicated in present application and composition obtained by the method indicated in the Omori '247 reference are not identical.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: This 7 day of April, 2009



[signature]

Toshiro OMORI

[Table 1] Ingredient composition of an unadsorbed fraction comprising a bypassed solution showing an unadsorptive property obtained by performing an adsorption separation process by passing the barley shochu stillage, as is, through a column filled with Amberlite XAD-16 (an aromatic synthetic adsorbent) (Composition A)

			Trial 1	Trial 2	Trial 3
Peptides	Constituent Amino Acid Content (weight %)		11.2	11.3	10.8
	Composition Ratio	Glutamic acid (%)	30.8	30.1	28.8
		Glycine (%)	13.6	13.3	13.1
		Aspartic acid (%)	7.8	7.8	7.5
		Proline (%)	7.1	6.8	6.5
		Serine (%)	5.9	6.1	5.7
Free Amino Acid	Free Amino Acids (weight %)		8.1	8.2	7.9
	Composition Ratio	Proline (%)	24.5	23.8	23.5
		Alanine (%)	14.2	14.2	13.9
		Leucine (%)	14.1	14.0	13.7
		Arginine (%)	13.8	13.6	13.1
		Glutamic acid (%)	16.8	16.6	16.1
Free Saccharides (weight %)			8.7	8.4	7.8
Glucose (weight %)			3.2	2.9	2.7
Xylose (weight %)			2.8	2.7	2.4
Arabinose (weight %)			2.1	1.9	1.8
Polysacharides (weight %)			22.3	22.8	20.4
Glucose (weight %)			9.1	9.2	8.1
Xylose (weight %)			5.8	6.3	5.5
Arabinose (weight %)			1.8	1.9	1.8
Organic Acids (weight %)			6.8	6.9	5.9

[Table 2] Ingredient composition of an unadsorbed fraction comprising a bypassed solution showing an unadsorptive property obtained by performing an adsorption separation process by passing the barley shochu stillage, as is, through a column filled with Amberlite XAD-7 (a methacryl synthetic adsorbent) (Composition B)

			Trial 1	Trial 2	Trial 3
Peptides	Constituent Amino Acid Content (weight %)		9.6	10.2	9.8
	Composition Ratio	Glutamic acid (%)	29.4	28.6	28.5
		Glycine (%)	11.1	10.8	10.9
		Aspartic acid (%)	7.2	7.3	7.1
		Proline (%)	6.8	6.4	6.2
		Serine (%)	5.6	5.8	5.2
Free Amino Acid	Free Amino Acids (weight %)		7.5	7.6	7.5
	Composition Ratio	Proline (%)	22.6	22.4	21.9
		Alanine (%)	13.7	13.9	13.7
		Leucine (%)	13.8	13.5	13.4
		Arginine (%)	12.7	13.3	12.4
		Glutamic acid (%)	14.8	15.2	15.0
Free Saccharides (weight %)			7.1	6.8	6.3
Glucose (weight %)			2.8	2.5	2.4
Xylose (weight %)			2.2	2.5	1.9
Arabinose (weight %)			1.5	1.6	1.4
Polysacharides (weight %)			19.8	20.5	18.8
Glucose (weight %)			9.3	8.9	9.1
Xylose (weight %)			5.6	5.4	5.0
Arabinose (weight %)			1.6	1.7	1.5
Organic Acids (weight %)			5.1	6.0	4.9

[Table 3] Ingredient composition of an unadsorbed fraction comprising a bypassed solution showing an unadsorptive property, obtained by performing an adsorption separation process by passing the barley shochu stillage, after condensed to 1/3, through a column filled with Sepabeads SP850 (an aromatic synthetic adsorbent) (Composition C)

			Trial 1	Trial 2	Trial 3
Peptides	Constituent Amino Acid Content (weight %)		12.8	12.4	12.3
	Composition Ratio	Glutamic acid (%)	31.8	32.3	31.4
		Glycine (%)	14.2	13.7	13.8
		Aspartic acid (%)	8.3	8.4	8.2
		Proline (%)	7.5	7.6	7.3
		Serine (%)	6.3	6.4	6.3
Free Amino Acid	Free Amino Acids (weight %)		9.3	9.1	8.7
	Composition Ratio	Proline (%)	29.8	28.7	28.5
		Alanine (%)	16.1	15.8	15.6
		Leucine (%)	15.0	15.1	14.8
		Arginine (%)	14.1	14.2	13.9
		Glutamic acid (%)	17.6	17.2	17.4
Free Saccharides (weight %)			10.2	9.7	9.5
Glucose (weight %)			4.5	4.2	4.3
Xylose (weight %)			3.4	3.3	3.0
Arabinose (weight %)			2.3	2.4	2.2
Polysacharides (weight %)			23.1	23.9	23.4
Glucose (weight %)			10.3	9.8	9.5
Xylose (weight %)			7.3	6.7	6.4
Arabinose (weight %)			2.2	2.2	2.1
Organic Acids (weight %)			10.3	11.2	10.9